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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,419	04/20/2004	Alfred Berchielli	PC25684A	5347
28880	7590	12/16/2008		
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 GROTON, CT 06340			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 12/16/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No. 10/828,419	Applicant(s) BERCHIELLI ET AL.	
	Examiner HASAN S. AHMED	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8-12 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,8-12 and 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Receipt is acknowledged of applicants': (1) amendment/response and (2) IDS, both filed on 4 September 2008.
- The previous 35 USC 103 rejection is withdrawn in view of the amendment.
- Applicants' arguments filed on 4 September 2008 have been considered but are moot in view of the new grounds of rejection.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation, "a mean particle size between 8 and 360 μm " is not disclosed in the instant specification (emphasis supplied). As such, said range limitation is deemed to be new matter.

*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the phrase "at least somewhat disordered" is vague and indefinite because it does not particularly point out and distinctly claim the level of atorvastatin disordering. Clarification is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 8-12, and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/072073 ("Kerc") in view of WO 01/76566 ("Fox").

Kerc teaches a solid unit dosage form of atorvastatin (see page 12, lines 11-15) comprising:

- the atorvastatin particles of instant claim 39 (see page 16, lines 3-5);
- the diluents of instant claim 39 (see page 11, lines 6-16);
- the tablet of instant claim 39 (see page 12, lines 11-15);
- the less than about 5% polymeric amide or polymeric amine additive of instant claims 7 and 32 (see Table 1, page 7 and Table 4, page 8);

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- the inorganic and organic bases of instant claims 31, 34 and 37 (see page 5, line 31);
- the less than 3% polymeric amide or polymeric amine of instant claim 40 (see Table 1, page 7 and Table 4, page 8); and
- the disordered (amorphous) atorvastatin of instant claims 4 and 40 (see abstract; page 5, lines 12-16; Tables 1 and 4; page 10, lines 8-13; and Examples 1-6).

Kerc explains that his composition is beneficial in providing therapeutic equivalence in atorvastatin pharmaceutical formulations (see page 3, lines 17-23).

The use of direct compression without a granulation step as recited in instant claim 39 is not essential to a determination of patentability of the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, “A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim.”

Kerc is silent with respect to potency, as recited in instant claim 39 and segregation number, as recited in instant claim 12. Applicants’ composition, as claimed, contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

While Kerc does not disclose the alkalizing agent additive concentration of instant claims 33, 36, and 39, it recites an alkalizing agent additive concentration as low

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as 10.4% (see Example 1, page 14). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05. Examiner respectfully submits that applicants have not shown that the properties of a formulation comprising 5% alkalizing agent would differ critically from a formulation comprising 10.4% alkalizing agent.

Kerc differs from the instant application in that it does not disclose the atorvastatin lactone levels of instant claims 8-11; however, the claimed levels were achieved in an atorvastatin pharmaceutical composition prior to the filing of the instant application (see Fox, example 4).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose solid unit dosage form comprising particulate atorvastatin, as taught by Kerc in view of Fox. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in therapeutic equivalence in atorvastatin pharmaceutical formulations, as explained by Kerc.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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